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EXAMINER	
COLON, CATHERINE M	
ART UNIT	**PAPER NUMBER**
3623	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/707,576	MAGNESS ET AL.
	Examiner	Art Unit
	C. Michelle Colon	3623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2000*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2, 3*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a Non-Final Office Action in response to the communication received on November 6, 2000. Claims 1-46 are now pending in this application.

Information Disclosure Statement

2. The examiner has reviewed the patents and publications supplied in the Information Disclosure Statement (IDS) provided on January 31, 2001 and April 16, 2003.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

(1) whether the invention is within the technological arts; and

(2) whether the invention produces a useful, concrete, and tangible result.

As per the first prong of the test, for a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences) and therefore are found

to be non-statutory subject matter. For a process claim to be satisfactory, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, the steps of method claims 1-40 only recite classifying a population based on medical histories and tests to determine individuals' risk and affected status for a biological condition; however, none of the steps apply, involve, use, or advance the technological arts since all of the recited steps can be performed in person or by use of a pencil and paper and without the need of a computer or other technology. These steps only constitute an idea of how to classify a population based on its medical histories and tests.

As per the second prong of the test, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention produces a classification system (i.e., concrete) based on individuals' medical histories and tests to determine their risk and affected status for a biological condition (i.e., useful and tangible).

Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 1-40 are directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-12, 14-18, 20-30, 32, 34-37, 39, 41-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Campell et al. (U.S. 6,059,724).

As per claim 1, Campell et al. discloses a method for the classification of a population, comprising:

analyzing medical histories of a population (col. 6, lines 12-51; The system analyzes a population's biomarker values over an extended period of time, or longitudinally.);

analyzing medical test results for the population (col. 6, lines 12-51; The system analyzes a population's medical test results, or measurement occasions, over a period of time.); and

based on the medical histories and the medical test results, classifying the population into one of the following sub-populations classifications for a selected biological condition (col. 10, lines 38-44; The system classifies individuals who are at risk for a particular biological condition, and predicts them as acquiring or not acquiring the biological condition.):

a. at risk and affected (ARA) by the selected biological condition (col. 18, lines 37-43 and 51-67; The system classifies individuals as being at (high) risk and predicted to be affected by the biological condition.); and

b. at risk and unaffected (ARU) by the selected biological condition (col. 18, lines 44-67; The system classifies individuals as being at (low) risk and predicted not to be affected by the biological condition.).

As per claim 2, Campell et al. discloses the method of claim 1, further comprising generating statistical data related to the medical histories and the medical test results wherein classifying the population comprises analyzing the statistical data (col. 6, lines 12-65; col. 7, lines 7-21; col. 17, lines 28-47; The system uses statistical methodologies to analyze a population's medical histories and test results.).

As per claim 3, Campell et al. discloses the method of claim 1, wherein analyzing medical histories comprises assigning numerical scores to selected conditions associated with the selected biological condition (col. 8, lines 10-62; col. 37, lines 16-28; Figure 1; The system plots the scores for the two populations indicating the scores for the populations' empirical distribution functions. The classification of individuals into the populations is based on analyses of both medical histories and test results. Mixed-model analysis is used to develop confidence levels (or scores) for biomarkers gathered in medical histories and test results.).

As per claim 4, Campell et al. discloses the method of claim 1, wherein analyzing medical test results comprises assigning numerical scores to selected medical tests associated with the selected biological condition (col. 8, lines 10-62; col. 37, lines 16-28; Figure 1; The system plots the scores for the two populations indicating the scores for the populations' empirical distribution functions. The classification of individuals into the populations is based on analyses of both medical histories and test results. Mixed-

model analysis is used to develop confidence levels (or scores) for biomarkers gathered in medical histories and test results.).

As per claim 5, Campell et al. discloses the method of claim 1, wherein analyzing medical histories and medical test results comprises assigning numerical scores to selected conditions associated with the selected biological condition and analyzing medical test results comprises assigning numerical scores to selected medical tests associated with the selected biological condition (col. 8, lines 10-62; col. 37, lines 16-28; Figure 1; The system plots the scores for the two populations indicating the scores for the populations' empirical distribution functions. Mixed-model analysis is used to develop confidence levels (or scores) for biomarkers gathered in medical histories and test results, where biomarkers with high confidence levels indicate a high predisposition to a particular biological condition.).

As per claims 6 and 7, Campell et al. discloses the method of claim 5, wherein classifying the population comprises evaluating the numerical scores for the medical histories and the medical test results; and combining the numerical scores for the medical histories and the medical test results and classifying the population based on the combined scores (col. 5, lines 1-58; Mixed-model analysis is used to develop confidence levels (or scores) for biomarkers gathered in medical histories and test results, where biomarkers with high confidence levels indicate a high predisposition/probability to a particular biological condition.).

As per claims 8 and 9, Campell et al. discloses the method of claim 5, further comprising generating statistical data related to the numerical scores for the medical

histories and the medical test results wherein classifying the population comprises analyzing the statistical data; and where the statistical data comprises generating a frequency distribution plot related to the numerical scores for the medical histories and the medical test results (col. 8, lines 10-62; col. 37, lines 16-28; Figure 1; The system plots the scores for the two populations indicating the scores for the populations' empirical distribution functions. The classification of individuals into the populations is based on analyses of both medical histories and test results. Mixed-model analysis is used to develop confidence levels (or scores) for biomarkers gathered in medical histories and test results.).

As per claims 10 and 11, Campell et al. discloses the method of claim 5, further comprising comparing the medical histories and the medical test results of the sub-population classified as ARU with the medical histories and the medical test results of the sub-population classified as ARA; and wherein the medical test results comprises genetic test results and comparing the genetic test results of the sub-population classified as ARU with the genetic test results of a selected portion of the sub-population classified as ARA (col. 13, lines 50-53; col. 19, lines 1-22).

As per claim 12, Campell et al. discloses the method of claim 11, further comprising determining genetic differences between genetic test results of the sub-population classified as ARU with the genetic test results of the sub-population classified as ARA (col. 19, lines 1-22; The system compares the biomarker values of each population, where the biomarker values are gathered from each populations medical histories and medical test results.).

As per claim 14, Campell et al. discloses the method of claim 1, further comprising selecting the portion of the sub-population classified as ARA and using the selected portion as a control group (col. 32, line 66-col. 33, line 14).

As per claim 15, Campell et al. discloses the method of claim 1, wherein classifying the population further comprises classifying the population into the ARA sub-population, the ARU sub-population or a sub-population classified as unknown risk and unaffected (URU) by the selected biological condition (col. 10, lines 38-44; col. 18, lines 37-67; col. 37, lines 16-38; The system classifies individuals who are at risk for a particular biological condition, and predicts them as acquiring or not acquiring the biological condition. The system also discloses that the term, prescribed low probability, can simply mean not being in the high risk group. The system also discloses that many subjects can be considered "borderline," and thus, difficult to classify.).

As per claims 16 and 17, Campell et al. discloses the method of claim 5, further comprising comparing the medical histories and the medical test results of the sub-population classified as ARU with the medical histories and the medical test results of the sub-population classified as URU; and wherein the medical test results comprises genetic test results and comparing the genetic test results of the sub-population classified as ARU with the genetic test results of a selected portion of the sub-population classified as URU (col. 13, lines 50-53; col. 19, lines 1-22; col. 37, lines 16-38;).

As per claim 18, Campell et al. discloses the method of claim 11, further comprising determining genetic differences between genetic test results of the sub-

population classified as ARU with the genetic test results of the sub-population classified as URU (col. 19, lines 1-22; col. 37, lines 16-38; The system compares the biomarker values of each population, where the biomarker values are gathered from each populations medical histories and medical test results.).

As per claim 20, Campell et al. discloses a method of data analysis to identify a selected population, comprising:

defining disease characteristics of a selected biological condition, including medical tests associated with the biological condition (col. 9, lines 31-48; The system uses biomarker data to define characteristics of a selected biological condition.);

analyzing medical test results based on medical tests performed on biological samples from a plurality of subjects with respect to the defined characteristics of the selected biological condition (col. 14, lines 8-32 and 41-55; The system analyzes biomarkers taken from medical tests.);

based on the analysis, determining the affected status of each of the plurality of subjects (col. 17, line 50-col. 18, line 12);

defining risk characteristics of the selected biological condition (col. 9, line 66-col. 10, line 56; The system uses biomarker values as risk characteristics of a selected biological condition.);

based on the risk characteristics, determining a risk status of each of the plurality of subjects (col. 9, line 66-col. 10, line 56; Based on an individual's biomarker values, the system determines their risk status.);

based on the affected status and the risk status, classifying each of the plurality of subjects into a predetermined category for the selected biological condition (col. 19, lines 1-22; col. 18, lines 13-50; The system classifies subjects based on their affected and risk status.).

As per claim 21, Campell et al. discloses the method of claim 20 wherein the defined disease characteristics of the selected biological condition have associated numerical scores and determining the affected status of each of the plurality of subjects comprises determining numerical scores based on the analysis of the medical test results (col. 8, lines 10-62; col. 37, lines 16-28; Figure 1; The system plots the scores for the two populations indicating the scores for the populations' empirical distribution functions. Mixed-model analysis is used to develop confidence levels (or scores) for biomarkers gathered in medical histories and test results, where biomarkers with high confidence levels indicate a high predisposition to a particular biological condition.).

As per claims 22 and 23, Campell et al. discloses the method of claim 20 wherein the defined risk characteristics of the selected biological condition have associated numerical scores and determining the risk status of each of the plurality of subjects comprises determining numerical scores; and wherein the defined disease characteristics of the selected biological condition have associated numerical scores and the defined risk characteristics of the selected biological condition have associated numerical scores, the classification of each of the plurality of subjects into a predetermined category being based on the numerical scores for affected and risk status (col. 8, lines 10-62; col. 37, lines 16-28; Figure 1; The system plots the scores for

the two populations indicating the scores for the populations' empirical distribution functions, which indicate affected and risk status. Mixed-model analysis is used to develop confidence levels (or scores) for biomarkers gathered in medical histories and test results, where biomarkers with high value indicate a high probability (or risk) to a particular biological condition.).

As per claim 24, Campell et al. discloses the method of claim 23, wherein the numerical scores for affected status and risk status are combined to form a combined score, the classification of each of the plurality of subjects into a predetermined category being based on the combined numerical scores for affected status and risk status (col. 32, line 25-col. 34, line 48; Tables 2 and 3; The references provides an example of where affected status (i.e., Disease Status) and risk status (i.e., Potential and Candidate Biomarker values) are combined and used to classify subjects.).

As per claim 25, Campell et al. discloses the method of claim 20, wherein the medical tests associated with the selected biological condition have varying degrees of relevance in defining the disease characteristics, the method further comprising assigning relevance weighting factors to the medical tests based on the degree of relevance, the affected status being based on the weighted medical tests (col. 33, lines 15-48; The reference discusses Potential and Candidate Biomarkers, which have varying degrees of relevance in defining the disease characteristics. For example, Candidate Biomarkers are considered "statistically significantly," based on previous research and experience, related to a particular disease.).

As per claim 26, Campell et al. discloses the method of claim 20, further comprising generating statistical data related to the affected status and risk status wherein classifying each of the plurality of subjects into a predetermined category comprises analyzing the statistical data (col. 33, line 15-col. 34, line 48; Table 3).

As per claim 27, Campell et al. discloses the method of claim 20, wherein the plurality of subjects are classified into a category selected from a group comprising at-risk, affected (ARA) and at risk unaffected (ARU) (col. 18, lines 13-50; col. 34, lines 12-48).

As per claims 28 and 29, Campell et al. discloses the method of claim 27, wherein risk status is determined at least in part from medical histories of the plurality of subjects, the method further comprising comparing the medical histories and the medical test results of the group of subjects classified as ARU with the medical histories and the medical test results of the group of subjects classified as ARA; and wherein the medical test results comprises genetic test results, the method further comprising comparing the genetic test results of the group of subjects classified as ARU with the genetic test results of the group of subjects classified as ARA (col. 13, lines 50-53; col. 19, lines 1-22).

As per claim 30, Campell et al. discloses the method of claim 29, further comprising determining genetic differences between genetic test results of the group of subjects classified as ARU with the genetic test results of the group of subjects classified as ARA (col. 19, lines 1-22; The system compares the biomarker values of

each population, where the biomarker values are gathered from each populations medical histories and medical test results.).

As per claim 32, Campell et al. discloses the method of claim 30, further comprising identifying a diagnostic assay based on the genetic differences between genetic test results of the group of subjects classified as ARU with the genetic test results of the group of subjects classified as ARA (col. 19, lines 35-51; The system identifies a diagnostic assay that is performed in three phases.).

As per claim 34, Campell et al. discloses the method of claim 20, wherein the plurality of subjects are classified into a category selected from the group comprising at-risk, affected (ARA), unknown risk, unaffected (URU), and at risk unaffected (ARU) (col. 10, lines 38-44; col. 18, lines 37-67; col. 37, lines 16-38; The system classifies individuals who are at risk for a particular biological condition, and predicts them as acquiring or not acquiring the biological condition. The system also discloses that the term, prescribed low probability, can simply mean not being in the high risk group. The system also discloses that many subjects can be considered "borderline," and thus, difficult to classify.).

As per claims 35 and 36, Campell et al. discloses the method of claim 34, wherein risk status is determined at least in part from medical histories of the plurality of subjects, the method further comprising comparing the medical histories and the medical test results of the group of subjects classified as ARU with the medical histories and the medical test results of the group of subjects classified as URU; and wherein the medical test results comprises genetic test results, the method further comprising

comparing the genetic test results of the group of subjects classified as ARU with the genetic test results of the group of subjects classified as URU (col. 13, lines 50-53; col. 19, lines 1-22).

As per claim 37, Campell et al. discloses the method of claim 36, further comprising determining genetic differences between genetic test results of the sub-population classified as ARU with the genetic test results of the sub-population classified as URU (col. 19, lines 1-22; col. 37, lines 16-38; The system compares the biomarker values of each population, where the biomarker values are gathered from each populations medical histories and medical test results.).

As per claim 39, Campell et al. discloses the method of claim 38, further comprising identifying a diagnostic assay based on the genetic differences between genetic test results of the group of subjects classified as ARU with the genetic test results of the group of subjects classified as URU (col. 19, lines 35-51; The system identifies a diagnostic assay that is performed in three phases.).

As per claim 41, Campell et al. discloses a system for data analysis to identify a selected population, comprising:

a affected status data structure containing numerical data defining disease characteristics of a selected biological condition, including medical tests associated with the selected biological condition (col. 9, line 31-col. 10, line 38; The system uses biomarker values to define characteristics of a selected biological condition.);

a disease risk data structure containing numerical data defining disease risk characteristics of the selected biological condition (col. 10, lines 1-44; Using the

biomarker values, a risk assessment can be made for an individual for a selected biological condition.); and

a processor to:

accept medical test results from a plurality of subjects and assign affected status numeric scores to the medical test results based on the numerical data defining disease characteristics of the selected biological condition (col. 10, lines 1-44; The system is a computer-based system that collects biomarker data to determine risk for an individual for a selected biological condition.);

store the affected status numeric scores for each of the subjects in the affected status data structure (col. 10, lines 1-44; col. 17, line 50-col. 18, line 12; The system acquires and stores data related to affected status (i.e., disease status) for a population.);

accept medical history data from a plurality of subjects and assign disease risk numeric scores to the medical history data based on the numerical data defining disease risk characteristics of the selected biological condition (col. 9, line 66-col. 10, line 56; Based on an individual's biomarker values, the system determines their risk status.);

store the disease risk numeric scores for each of the subjects in the disease risk data structure (col. 9, line 66-col. 10, line 56; The system uses biomarker values as risk characteristics of a selected biological condition.); and

determine a affected status and risk status for each of the subjects based on the respective affected status numeric scores and the disease risk numeric scores (col. 19,

lines 1-22; col. 18, lines 13-50; The system classifies subjects based on their affected and risk status.).

As per claim 42, Campell et al. discloses the system of claim 41, wherein the processor combines the numerical scores for affected status and risk status to form a combined numerical score, the processor further classifying of each of the plurality of subjects into a predetermined category being based on the combined numerical scores for affected status and risk status (col. 32, line 25-col. 34, line 48; Tables 2 and 3; The references provides an example of where affected status (i.e., Disease Status) and risk status (i.e., Potential and Candidate Biomarker values) are combined and used to classify subjects.).

As per claim 43, Campell et al. discloses the system of claim 41, wherein the medical tests associated with the selected biological condition have varying degrees of relevance in defining the disease characteristics, the processor further assigning relevance weighting factors to the medical tests based on the degree of relevance, the processor determining the affected status based on the weighted medical tests (col. 33, lines 15-48; The reference discusses Potential and Candidate Biomarkers, which have varying degrees of relevance in defining the disease characteristics. For example, Candidate Biomarkers are considered "statistically significantly," based on previous research and experience, related to a particular disease.).

As per claim 44, Campell et al. discloses the system of claim 41, wherein the processor further generates statistical data related to the affected status and risk status, the processor further classifying of each of the plurality of subjects into a predetermined

category being based on analysis of the statistical data (col. 33, line 15-col. 34, line 48; Table 3).

As per claim 45, Campell et al. discloses the system of claim 41, wherein the processor further classifies each of the plurality of subjects into a predetermined category selected from a group of categories comprising at-risk, affected (ARA) and at risk unaffected (ARU) (col. 18, lines 13-50; col. 34, lines 12-48).

As per claim 46, Campell et al. discloses the system of claim 41, wherein the processor further classifies each of the plurality of subjects into a predetermined category selected from the group of categories comprising at-risk, affected (ARA), unknown risk, unaffected (URU), and at risk unaffected (ARU) (col. 10, lines 38-44; col. 18, lines 37-67; col. 37, lines 16-38; The system classifies individuals who are at risk for a particular biological condition, and predicts them as acquiring or not acquiring the biological condition. The system also discloses that the term, prescribed low probability, can simply mean not being in the high risk group. The system also discloses that many subjects can be considered "borderline," and thus, difficult to classify.).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 13, 19, 31, 33, 38 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campell et al. (U.S. 6,059,724).

As per claims 13, 19, 31, 33, 38 and 40, Campell et al. does not expressly disclose the method of claims 12, 18, 30, 37 and 38, further comprising identifying genetic drug targets or vaccine component based on the genetic differences between genetic test results of the sub-population classified as ARU with the genetic test results of the sub-population classified as ARA or URU. However, Campell et al. does disclose comparing the biomarker values of the populations (col. 19, lines 1-22) in order to identify potentially important discriminants for a selected biological condition (col. 21, lines 24-33). Thus, if a discriminant such as serum cholesterol or systolic blood pressure can be identified, it is well known in the art to identify which drugs are used for those discriminants. At the time of the invention, it would have been obvious to a person of ordinary skill in the art for the system of Campell et al. to identify drug targets associated with the discriminants because doing so would be in line with the goal of the system of Campell et al., which is to identify biomarkers that predict a high probability for a biological condition and, in turn, provide an individual with the means (such as a drug or lifestyle change) to combat the biomarker so as not to acquire the biological condition.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Matson (U.S. 4,863,873) discusses a method for biological testing; and
- Kristal et al. (U.S. 6,558,955) discusses methodology for predicting and/or diagnosing disease.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Michelle Colon whose telephone number is 703-605-4251. The examiner can normally be reached Monday – Friday from 8:30am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tariq Hafiz, can be reached at 703-305-9643.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington D.C. 20231

or faxed to:

703-872-9306 [Official Communications; including After Final communications labeled "Box AF"]

703-746-7202 [For status inquiries, draft communication, labeled "Proposed" or "Draft"]

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA 7th floor receptionist.

cmc
June 12, 2004

TARIQ R. HAFIZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600